- (1) Tangible net worth at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.
- (2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.
- (3) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.
- B. To pass the financial test, a company must meet all of the following additional requirements:
- (1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.
- (2) The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform NRC within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.
- (3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.
- C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the Commission of its intent to establish alternate financial assurance as specified in the Commission's regulations within 120 days of such notice.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Commission. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Commission, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in the Commission's regulations within 90 days following receipt by the Commission of a notice of cancellation of the guarantee.

- C. The guarantee and financial test provisions must remain in effect until the Commission has terminated the license or until another financial assurance method acceptable to the Commission has been put in effect by the licensee.
- D. The licensee will promptly forward to the Commission and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.
- E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Commission within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of Section II.A. of this appendix.
- F. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

[58 FR 68730, Dec. 29, 1993; 59 FR 1618, Jan. 12, 1994]

PART 31—GENERAL DOMESTIC LI-CENSES FOR BYPRODUCT MATE-RIAL

Sec.

- 31.1 Purpose and scope.
- 31.2 Terms and conditions.
- 31.3 Certain devices and equipment.
- 31.4 Information collection requirements: OMB approval.
- 31.5 Certain measuring, gauging or controlling devices.
- 31.6 General license to install devices generally licensed in § 31.5.
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- 31.8 Americium-241 in the form of calibration or reference sources.
- 31.9 General license to own byproduct material.
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- material for certain in vitro clinical or laboratory testing.
- 31.12 Maintenance of records.
- 31.13 Violations.
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§ 31.1

AUTHORITY: Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended (42 U.S.C. 2111, 2201, 2233); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842).

Section 31.6 also issued under sec. 274, 73 Stat. 688 (42 U.S.C. 2021).

§31.1 Purpose and scope.

This part establishes general licenses for the possession and use of byproduct material contained in certain items and a general license for ownership of byproduct material. Part 30 of this chapter also contains provisions applicable to the subject matter of this part.

[35 FR 6428, Apr. 22, 1970]

§31.2 Terms and conditions.

(a) The general licenses provided in this part are subject to the provisions of §§ 30.14(d), 30.34(a) to (e), 30.41, 30.50 to 30.63 and parts 19, 20, and 21 of this chapter¹ unless indicated otherwise in the language of the general license.

(b) [Reserved]

[38 FR 22220, Aug. 17, 1973, as amended at 38 FR 33969, Dec. 10, 1973; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 40767, Aug. 16, 1991]

§31.3 Certain devices and equipment.

A general license is hereby issued to transfer, receive, acquire, own, possess and use byproduct material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued to him by the Commission.

(a) Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries of polonium 210 per device.

(b)-(c) [Reserved]

(d) Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries of polonium 210 per device or of a total of

not more than 50 millicuries of hydrogen 3 (tritium) per device.

[30 FR 8189, June 26, 1965, as amended at 34 FR 6652, Apr. 18, 1969; 35 FR 3982, Mar. 3, 1970]

§31.4 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150–0016.

(b) The approved information collection requirements contained in this part appear in §§31.5, 31.6, 31.8, and 31.11.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §31.11. NRC Form 483 is approved under control number 3150-0038.
(2) [Reserved]

[62 FR 52186, Oct. 6, 1997]

§31.5 Certain measuring, gauging or controlling devices.²

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs (b), (c) and (d) of this section, byproduct material contained in devices designed and manufactured for

¹ Attention is directed particularly to the provisions of the regulations in part 20 of this chapter which relate to the labeling of containers

²Persons possessing byproduct material in devices under the general license in §31.5 before Jan. 15, 1975, may continue to possess, use or transfer that material in accordance with the requirements of §31.5 in effect on Jan. 14, 1975.

the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

- (b) The general license in paragraph (a) of this section applies only to byproduct material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued pursuant to §32.51 of this chapter or in accordance with the specifications contained in a specific license issued by an Agreement State which authorizes distribution of the devices to persons generally licensed by the Agreement State.
- (c) Any person who acquires, receives, possesses, uses or transfers by-product material in a device pursuant to the general license in paragraph (a) of this section:
- (1) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;
- (2) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:
- (i) Devices containing only krypton need not be tested for leakage of radioactive material, and
- (ii) Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emiting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;
- (3) Shall assure that the tests required by paragraph (c)(2) of this section and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

- (i) In accordance with the instructions provided by the labels; or
- (ii) By a person holding a specific license pursuant to parts 30 and 32 of this chapter or from an Agreement State to perform such activities;
- (4) Shall maintain records showing compliance with the requirements of paragraphs (c)(2) and (c)(3) of this section. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:
- (i) Each record of a test for leakage or radioactive material required by paragraph (c)(2) of this section must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.
- (ii) Each record of a test of the on-off mechanism and indicator required by paragraph (c)(2) of this section must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of
- (iii) Each record that is required by paragraph (c)(3) of this section must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.
- (5) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license pursuant to parts 30 and 32 of this chapter or from an Agreement State to repair such devices, or disposed of by transfer to a person authorized by a specific license to receive the byproduct material contained in the device and, within 30 days, furnish to the Administrator of the appropriate Nuclear Regulatory Commission, Regional Office listed in appendix D of part 20 of this chapter, a

report containing a brief description of the event and the remedial action taken:

- (6) Shall not abandon the device containing byproduct material;
- (7) Shall not export the device containing byproduct material except in accordance with part 110 of this chapter;
- (8) Except as provided in paragraph (c)(9) of this section, shall transfer or dispose of the device containing byproduct material only by transfer to persons holding a specific license pursuant to parts 30 and 32 of this chapter or from an Agreement State to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

(9) Shall transfer the device to another general licensee only:

(i) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this section and any safety documents identified in the label of the device and within 30 days of the transfer, report to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Commission and the transferee; or

(ii) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee.

(10) Shall comply with the provisions of §§ 20.2201, and 20.2202 of this chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of parts 19, 20, and 21, of this chapter.

(d) The general license in paragraph (a) of this section does not authorize

the manufacture or import of devices containing byproduct material.

[39 FR 43532, Dec. 16, 1974, as amended at 40 FR 8785, Mar. 3, 1975; 40 FR 14085, Mar. 28, 1975; 42 FR 25721, May 19, 1977; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 53 FR 19246, May 27, 1988; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993]

§31.6 General license to install devices generally licensed in § 31.5.

Any person who holds a specific license issued by an Agreement State authorizing the holder to manufacture, install, or service a device described in §31.5 within such Agreement State is hereby granted a general license to install and service such device in any non-Agreement State and a general license to install and service such device in offshore waters, as defined in §150.3(f) of this chapter: *Provided*, That:

(a) [Reserved]

- (b) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Agreement State.
- (c) Such person assures that any labels required to be affixed to the device under regulations of the Agreement State which licensed manufacture of the device bear a statement that removal of the label is prohibited.

[30 FR 8189, June 26, 1965, as amended at 30 FR 10947, Aug. 24, 1965; 39 FR 43533, Dec. 16, 1974; 46 FR 44151, Sept. 3, 1981]

§31.7 Luminous safety devices for use in aircraft.

(a) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided each device contains not more than 10 curies of tritium or 300 millicuries of promethium-147 and that each device has been manufactured, assembled or initially transferred in accordance with a license issued under the provisions of §32.53 of this chapter or manufactured or assembled in accordance with a specific license issued by an Agreement State which authorizes manufacture or assembly of the device for distribution to persons generally licensed by the Agreement State.

- (b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in this section are exempt from the requirements of parts 19, 20, and 21, of this chapter, except that they shall comply with the provisions of §§ 20.2201, and 20.2202 of this chapter.
- (c) This general license does not authorize the manufacture, assembly, repair or import of luminous safety devices containing tritium or promethium-147.
- (d) This general license does not authorize the export of luminous safety devices containing tritium or promethium-147.
- (e) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

[30 FR 8189, June 26, 1965, as amended at 33 FR 6463, Apr. 27, 1968; 38 FR 22220, Aug. 17, 1973; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993]

§ 31.8 Americium-241 in the form of calibration or reference sources.

- (a) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of paragraphs (b) and (c) of this section, americium-241 in the form of calibration or reference sources:
- (1) Any person in a non-Agreement State who holds a specific license issued pursuant to this chapter which authorizes him to receive, possess, use and transfer byproduct material, source material, or special nuclear material; and
- (2) Any Government agency, as defined in $\S 30.4(g)$ of this chapter, which holds a specific license issued pursuant to this chapter which authorizes it to receive, possess, use and transfer byproduct material, source material, or special nuclear material.
- (b) The general license in paragraph (a) of this section applies only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued pursuant to §32.57 of this chapter or in accordance with the specifications contained in a specific li-

cense issued to the manufacturer by an Agreement State which authorizes manufacture of the sources for distribution to persons generally licensed by the Agreement State.

- (c) The general license in paragraph (a) of this section is subject to the provisions of §§ 30.14(d), 30.34 (a) to (e), and 30.50 to 30.63 of this chapter, and to the provisions of parts 19, 20, and 21, of this chapter. In addition, persons who own, receive, acquire, possess, use and transfer one or more calibration or reference sources pursuant to this general license:
- (1) Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of americium-241 in such sources:

(2) Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement: ¹

The receipt, possession, use and transfer of this source, Model ___, Serial No. ___, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL— THIS SOURCE CONTAINS AMERICIUM-241. DO NOT TOUCH RADIOACTIVE POR-TION OF THIS SOURCE.

(Name of manufacturer or initial transferor)

- (3) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license pursuant to this chapter or from an Agreement State to receive the source.
- (4) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium—241 which might otherwise escape during storage.
- (5) Shall not use such source for any purpose other than the calibration of

¹ Sources generally licensed under this section prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

radiation detectors or the standardization of other sources.

- (d) This general license does not authorize the manufacture or import of calibration or reference sources containing americium-241.
- (e) This general license does not authorize the export of calibration or reference sources containing americium-

[30 FR 8189, June 26, 1965, as amended at 38 FR 22220, Aug. 17, 1973; 40 FR 8785, Mar. 3, 1975; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 40767, Aug. 16, 1991]

§31.9 General license to own byproduct material.

A general license is hereby issued to own byproduct material without regard to quantity. Notwithstanding any other provision of this chapter, a general licensee under this paragraph is not authorized to manufacture, produce, transfer, receive, possess, use, import or export byproduct material, except as authorized in a specific license.

[30 FR 8189, June 26, 1965]

§31.10 General license for strontium 90 in ice detection devices.

- (a) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium 90 contained in ice detection devices, provided each device contains not more than fifty microcuries of strontium 90 and each device has been manufactured or initially transferred in accordance with the specifications contained in a license issued pursuant to §32.61 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by an Agreement State which authorizes manufacture of the ice detection devices for distribution to persons generally licensed by the Agreement State.
- (b) Persons who own, receive, acquire, possess, use, or transfer strontium 90 contained in ice detection devices pursuant to the general license in paragraph (a) of this section:
- (1) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected,

tested for leakage and repaired by a person holding a specific license pursuant to part 30 or 32 of this chapter or from an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of §20.2001.

- (2) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon:
- (3) Are exempt from the requirements of parts 19, 20, and 21, of this chapter except that such persons shall comply with the provisions of §§ 20.2001, 20.2201, and 20.2202 of this chapter.
- (c) The general license does not authorize the manufacture, assembly, disassembly, repair, or import of strontium 90 in ice detection devices.

[30 FR 9905, Aug. 10, 1965, as amended at 38 FR 22220, Aug. 17, 1973; 40 FR 8785, Mar. 3, 1975; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993]

§31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

- (a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:
- (1) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals
- (2) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.
- (3) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation

therefrom, to human beings or animals.

- (4) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.
- (5) Iron-59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings, or animals.
- (6) Selenium-75, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.
- (7) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.
- (b) A person shall not receive, acquire, possess, use, or transfer byproduct material under the general license established by paragraph (a) of this section unless that person:
- (1) Has filed Form NRC-483, "Registration Certificate—In Vitro Testing with Byproduct Material Under General License," with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 and received from the Commission a validated copy of Form NRC-483 with a registration number assigned; or
- (2) Has a license that authorizes the medical use of byproduct material that was issued under part 35 of this chapter.
- (c) A person who receives, acquires, possesses, or uses byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:
- (1) The general licensee shall not possess at any one time, pursuant to the general license in paragraph (a) of this

- section, at any one location of storage or use, a total amount of iodine 125, iodine 131, selenium-75, and/or iron-59 in excess of 200 microcuries.
- (2) The general licensee shall store the byproduct material, until used, in the original shipping container or in a container providing equivalent radiation protection.
- (3) The general licensee shall use the byproduct material only for the uses authorized by paragraph (a) of this section.
- (4) The general licensee shall not transfer the byproduct material except by transfer to a person authorized to receive it by a license pursuant to this chapter or from an Agreement State, nor transfer the byproduct material in any manner other than in the unopened, labeled shipping container as received from the supplier.
- (5) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in paragraph (a)(7) of this section as required by §20.2001.
- (d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:
- (1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of §32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State that authorizes manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, or Mock Iodine-125 for distribution to persons generally licensed by the Agreement State.
- (2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package: ¹

¹Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.

§ 31.12

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of Manufacturer)

- (e) The registrant possessing or using byproduct materials under the general license of paragraph (a) of this section shall report in writing to the Director of Nuclear Material Safety and Safeguards, any changes in the information furnished by him in the "Registration Certificate—In Vitro Testing With Byproduct Material Under General License". Form NRC-483. The report shall be furnished within 30 days after the effective date of such change.
- (f) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of parts 19, 20, and 21, of this chapter with respect to byproduct materials covered by that general license, except that such persons using the Mock Iodine-125 described in paragraph (a)(7) of this section shall comply with the provisions of §§ 20.2001, 20.2201, and 20.2202.

[33 FR 16553, Nov. 14, 1968, as amended at 38 FR 1271, Jan. 11, 1973; 38 FR 34110, Dec. 11, 1973; 39 FR 26147, July 17, 1974; 40 FR 8785, Mar. 3, 1975; 41 FR 16446, Apr. 19, 1976; 42 FR 21604, Apr. 28, 1977; 42 FR 26987, May 26, 1977; 42 FR 28896, June 6, 1977; 44 FR 50325, Aug. 28, 1979; 51 FR 36967, Oct. 16, 1986; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993]

§31.12 Maintenance of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention pe-

riod. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as letters, stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[53 FR 19246, May 27, 1988]

§31.13 Violations.

- (a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—
- (1) The Atomic Energy Act of 1954, as amended;
- (2) Title II of the Energy Reorganization Act of 1974, as amended; or
- (3) A regulation or order issued pursuant to those Acts.
- (b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:
- (1) For violations of-
- (i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;
- (ii) Section 206 of the Energy Reorganization Act:
- (iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section:
- (iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.
- (2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55072, Nov. 24, 1992]

§31.14 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 31 are issued under one or more of sections 161b, 161i, or

1610, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 31 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§31.1, 31.2, 31.3, 31.4, 31.9, 31.13, and 31.14.

[57 FR 55073, Nov. 24, 1992]

PART 32—SPECIFIC DOMESTIC LI-CENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CON-TAINING BYPRODUCT MATERIAL

Sec.

- 32.1 Purpose and scope.
- 32.2 Definitions.
- 32.3 Maintenance of records.
- 32.8 Information collection requirements: OMB approval.

Subpart A—Exempt Concentrations and Items

- 32.11 Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license.
- 32.12 Same: Records and material transfer reports.
- 32.13 Same: Prohibition of introduction.
- 32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.
- 32.15 Same: Quality assurance, prohibition of transfer, and labeling.
- 32.16 Certain items containing byproduct material: Records and reports of transfer.
- 32.17 Resins containing scandium-46 and designed for sand-consolidation in oil wells: Requirements for license to manufacture, or initially transfer for sale or distribution.
- 32.18 Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license.
- 32.19 Same: Conditions of licenses
- 32.20 Same: Records and material transfer reports.
- 32.21 Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for "in vivo" diagnostic use for humans to persons exempt from licensing; Requirements for a license.
- 32.21a Same: Conditions of license.
- 32.22 Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer.
- 32.23 Same: Safety criteria.
- 32.24 Same: Table of organ doses.

- 32.25 Conditions of licenses issued under §32.22: Quality control, labeling, and reports of transfer.
- 32.26 Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.
- 32.27 Same: Safety criteria.
- 32.28 Same: Table of organ doses.
- 32.29 Conditions of licenses issued under §32.26: Quality control, labeling, and reports of transfer.
- 32.40 Schedule A—Prototype tests for automobile lock illuminators.

Subpart B—Generally Licensed Items

- 32.51 Byproduct material contained in devices for use under §31.5; requirements for license to manufacture or initially transfer.
- 32.51a Same: Conditions of licenses.
- 32.52 Same: Material transfer reports and records.
- 32.53 Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer.
- 32.54 Same: Labeling of devices.
- 32.55 Same: Quality assurance; prohibition of transfer.
- 32.56 Same: Material transfer reports.
- 32.57 Calibration or reference sources containing americium-241: Requirements for license to manufacture or initially transfer.
- 32.58 Same: Labeling of devices.
- 32.59 Same: Leak testing of each source.
- 32.60 [Reserved]
- 32.61 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.
- 32.62 Same: Quality assurance; prohibition of transfer.
- 32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.
- 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.
- 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.
- 32.101 Schedule B—prototype tests for luminous safety devices for use in aircraft.
- 32.102 Schedule C—prototype tests for calibration or reference sources containing americium-241.
- 32.103 Schedule D—prototype tests for ice detection devices containing strontium 90.